

PureClear™ Inspection Scope

In-Service Guide



ENHANCING VISUAL INSPECTION

Magnification • Illumination • Visualization • Documentation

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PROCESSING

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PureClear™ Inspection Scopes and Accessories

Intended Use

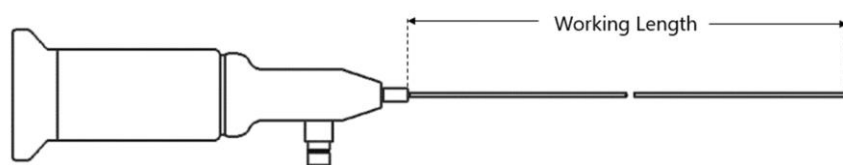
The *PureClear Inspection Scope* is used for visual inspection of medical devices during reprocessing.

Do not set up or use the PureClear Inspection Scope, products or accessories before reading the instructions for use and/or package inserts included with each product, as not all warnings and precautions are addressed in this In-Service Guide.

PureClear Inspection Scopes

Model	Description	Outer Diameter	Working Length	Recommended for:	Examples:
C1-800	PureClear Inspection Scope, Mini	0.86 mm	80 cm	Areas ≥ 1 mm diameter and ≤ 160 cm length*	Very thin channels (bronchoscopes, ureteroscopes, ENT, cystoscopes, etc.)
C2-350	PureClear Inspection Scope, Short	1.9 mm	35 cm	Areas ≥ 2 mm diameter and ≤ 70 cm length*	Most common instrument is CSD (surgical instruments, arthroscopic shavers, suction tubes, etc.)
C2-950	PureClear Inspection Scope, Long	1.9 mm	95 cm	Areas ≥ 2 mm diameter and ≤ 190 cm length*	Common GI Scopes (colonoscopes, duodenoscopes – behind elevator, robotic instruments, etc.)

*If able to be inserted from both directions



PureClear™ Inspection Scope Accessories

Model	Description
5197-202	PureClear™ Inspection LED Light Source
5163-100	Light Cable, ACMI - ACMI, 1 mm
237HD	Flexible Arm, Manfrotto, 520 mm
386BC-1	Nano Clamp, Manfrotto
635	Super Clamp, Manfrotto
GT405	Digital Camera, Firefly™



PureClear™ Inspection LED
Light Source



Flexible Arm



Super Clamp



Light Cable

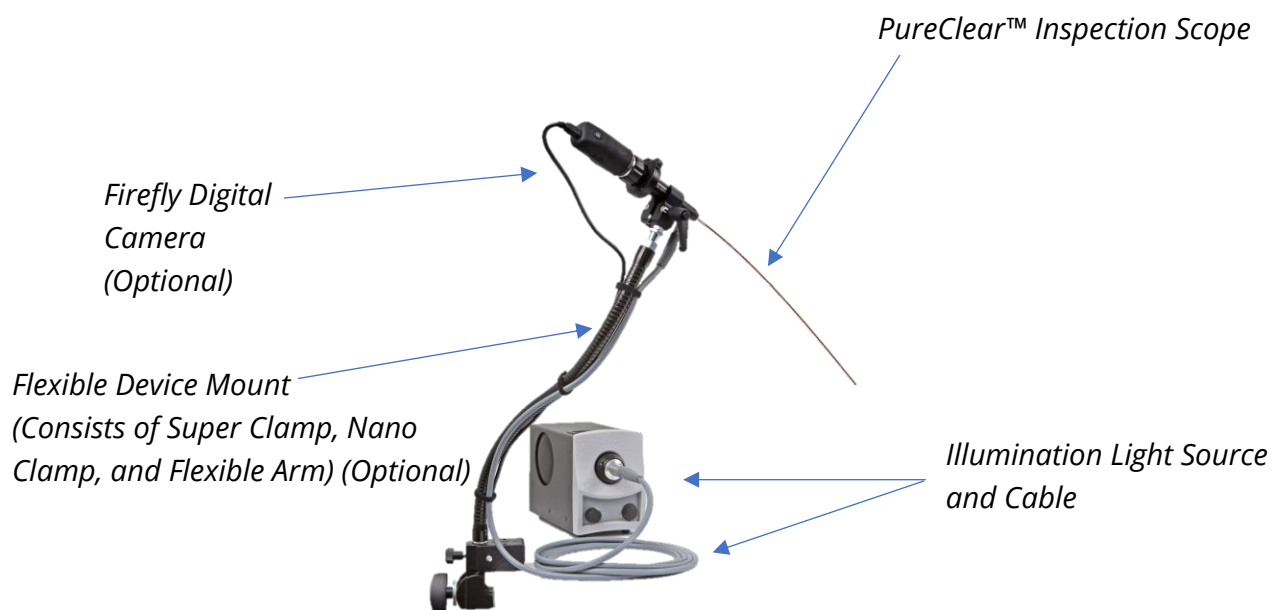


Nano Clamp



Firefly™
Digital
Camera

Complete *PureClear Inspection Scope* Workstation



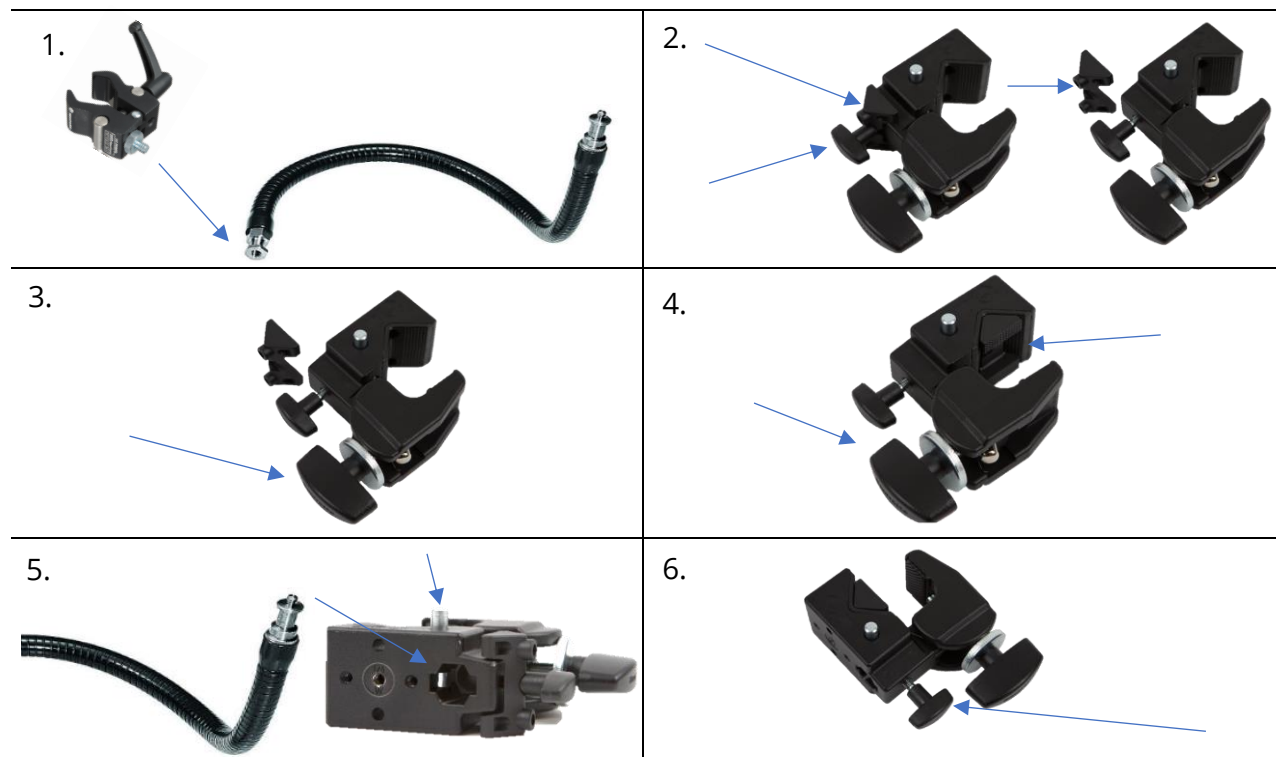
Setting Up Your PureClear™ Inspection Scope Workstation

Flexible Device Mount Setup

The *Flexible Device Mount* features a *Flexible Arm* and *Clamps* from Manfrotto, which hold the *PureClear Inspection Scope* so the user can use both hands and make quick adjustments to position it ergonomically. Although it is an optional accessory, Pure Processing strongly recommends this or a similar adjustable mount.

Setup

1. Begin by screwing the *Nano Clamp* into the *Flexible Arm* until tight.
2. Loosen the small knob, remove the *Wedge* from the small knob of the *Super Clamp* and place in the groove located on the inside of the *Super Clamp*.
 - a. NOTE: Only preform Step 2 if placing on a tabletop surface. If planting on a rounded or cylindrical object, leave wedge in place
3. Loosen the large, plastic knob on the *Super Clamp*.
4. Place the mouth of the *Super Clamp* on the table with the large knob on bottom, and fasten large knob until firmly secured on the table.
5. Press and hold the silver button located on the *Super Clamp* and place the flexible arm end opposite the *Nano Clamp* into the hole near the back.
6. Tighten the smaller knob on the *Super Clamp* to secure the *Flexible Arm*.

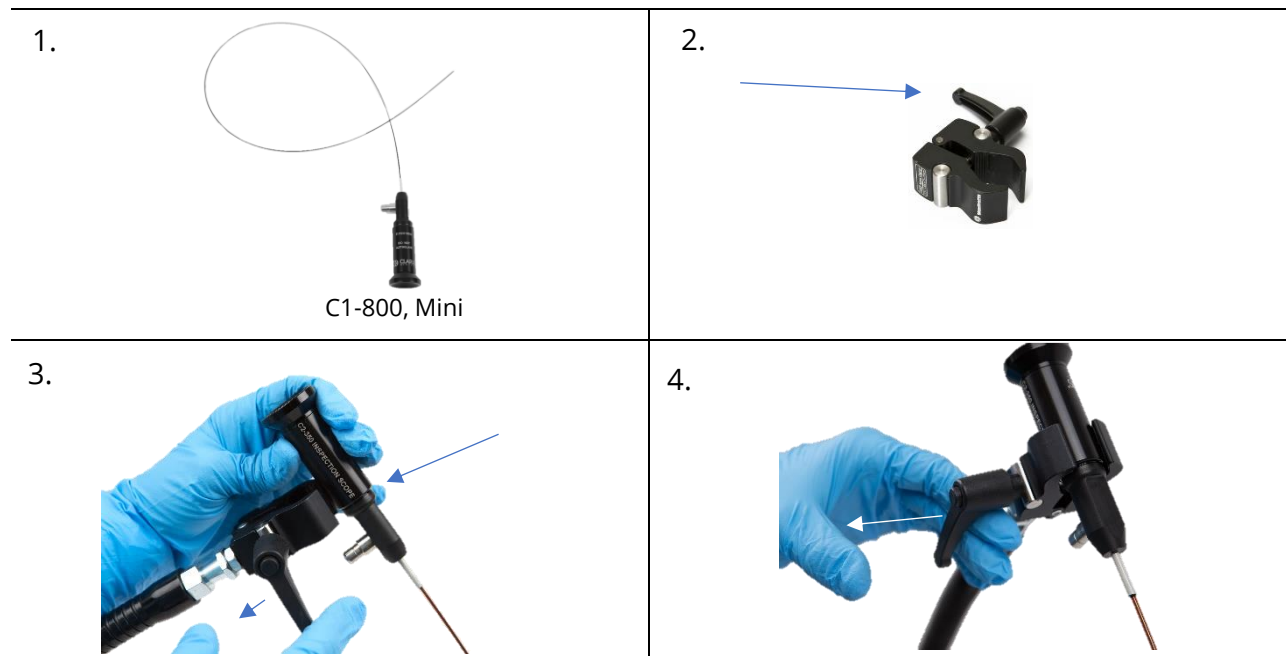


PureClear™ Inspection Scope Setup

This section will address how to attach the *PureClear Inspection Scope* to a Manfrotto *Flexible Device Mount*.

Setup

1. Remove plastic sheath covering the *PureClear Inspection Scope* if using the PureClear Model C1-800, Mini.
2. Loosen the *Nano Clamp* by using the large black lever located on its side.
3. Carefully take the *PureClear Inspection Scope* and place into the *Nano Clamp* so that the silver light source connector faces down.
 - a. NOTE: The logo and the serial number should both be visible.
4. Tighten the *Nano Clamp* until the *PureClear Inspection Scope* is secure.
 - a. NOTE: To reposition the *Nano Clamp* lever without affecting the lock, pull out on the lever and rotate as seen in Step 4.



Illumination Setup

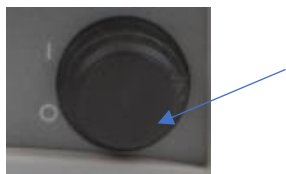
The *PureClear™ Inspection LED Light Source* delivers high intensity illumination through a non-electrical fiber-optic cable passed through the *PureClear Inspection Scope*.

PureClear Inspection LED Light Source and Light Cable may be hot after use and may cause injury if handled improperly. Please allow 5 minutes minimum for the PureClear Inspection LED Light Source and Light Cable to cool before disassembling to ensure they have cooled properly. Do not point the PureClear Light Source, Light Cable or illuminated end of the PureClear Inspection Scope towards eyes when the Light Source is powered on.

Setup

1. Insure the *PureClear Inspection LED Light Source* is turned off before setup.
 - a. NOTE: To accomplish this, press the lower half of the button towards the 'O' symbol.
2. Next, plug the power cable into the back of the *PureClear Inspection LED Light Source* then into outlet.
3. Plug the *Light Cable* into the *PureClear Inspection LED Light Source*
4. Attach the other end of the *Light Cable* to light cable port on *PureClear Inspection Scope* until you hear a click.
5. Press the power button to power on the *PureClear Inspection LED Light Source*.
 - a. NOTE: To accomplish this press the upper half of the button towards the 'I' symbol.
6. You can use the dimmer switch to control light output.

1.



2.



3.



4.



5.



6.



Firefly™ Digital Camera Setup

The Firefly Digital Camera is intended to aid in the inspection process by allowing the user to view the magnified image on a monitor and capture photos and video.

Prerequisites:

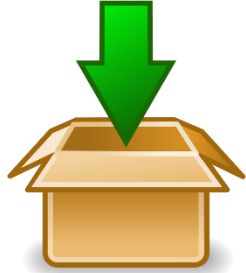
- Display monitor
- Computer or Laptop
 - Windows® 7 (or later) or OS X 10.8 (or later)
 - CD Drive or Internet Connectivity
 - USB Port 2.0 (or higher)

Setup

(Images for this Step-by-Step are located on the next page)

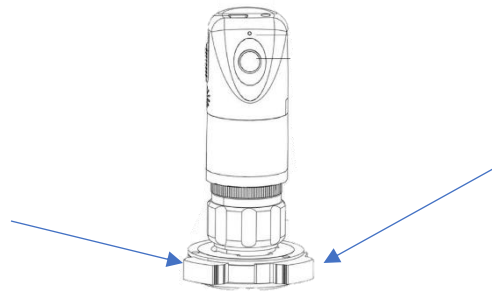
1. When using the *Firefly Digital Camera* for the first time, use the CD provided to install the software, then follow the prompts provided by the software. Alternatively, you can also download the software from the Firefly website directly at www.fireflyglobal.com/downloads.
 - a. NOTE: If asked what device to install, the model is GT405.
 - b. NOTE: Please allow between 1-10 minute(s) for the software to download and/or install.
2. Remove the protective lens cover from the *Firefly Digital Camera* by squeezing the connector tabs together.
3. To attach the lens to the eyepiece, again, squeeze the connector tabs together
4. While holding the connector tabs, place the *Firefly Digital Camera* onto the *PureClear™ Inspection Scope* and release the connector tabs.
5. Connect the Mini USB cable to your *Firefly Digital Camera*.
6. Plug the USB 2.0 end of the cable into your computer.
7. Find the power switch on the side of the *Firefly Digital Camera* and slide it to LED.
8. Open the Firefly software by double clicking the Firefly Icon that should be on your desktop. An image should appear in a window in the Firefly application.

1.



Download & Install
Firefly Viewing Software

2.



Connector Tabs

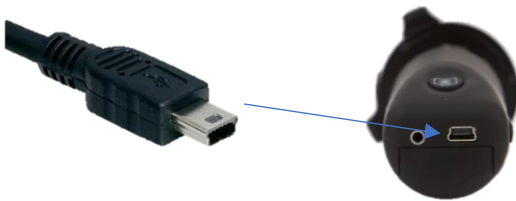
3.



4.



5.



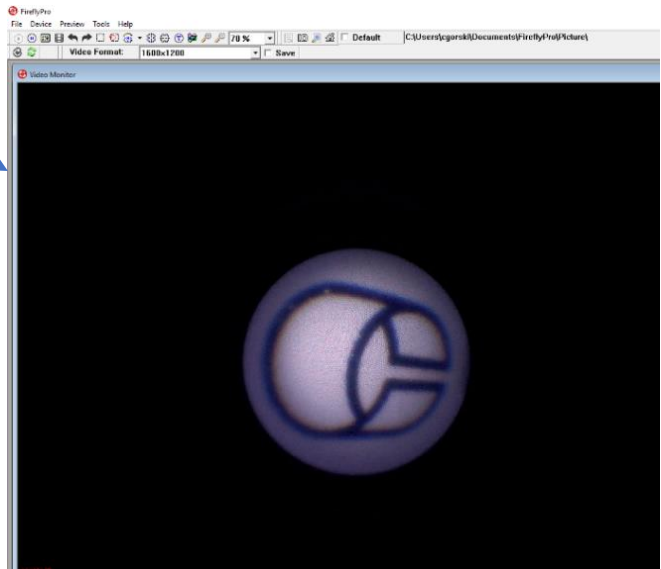
6.



7.



8.



Firefly™ Digital Camera Use

Calibrating the Camera

Before using your *Firefly Digital Camera*, you need to focus and orient it. To focus the camera, turn the focus wheel on the camera. To orient the image, turn the camera itself.

Place your scope 5 mm away from the image located below to help focus your scope. Print this page in black and white for clearest image.

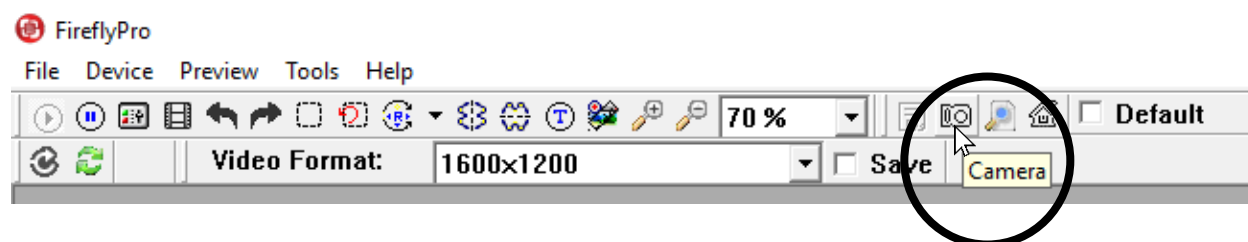


1. Turn the focus wheel until you see the honeycomb shaped pixels.
2. Turn just slightly past that point to smooth out the pixels.
3. Adjust the camera so the image appears upright.

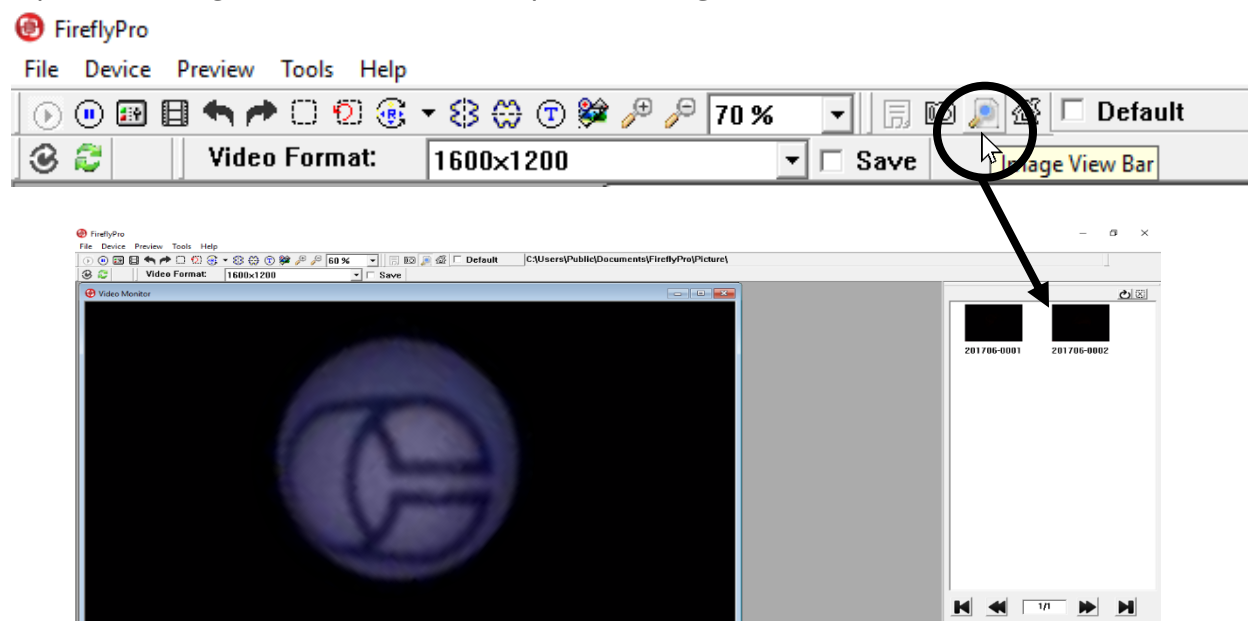


Using the Firefly Software

In addition to the ability to view the image on a monitor, the Firefly camera enables the user to document by capturing photos or video. The tool bar at the top of the software enables quick access to various functions. The Firefly GT 405 Digital Camera User Manual describes the various functions of the icons, or you can hover your cursor over the icon for a brief description (as shown below).



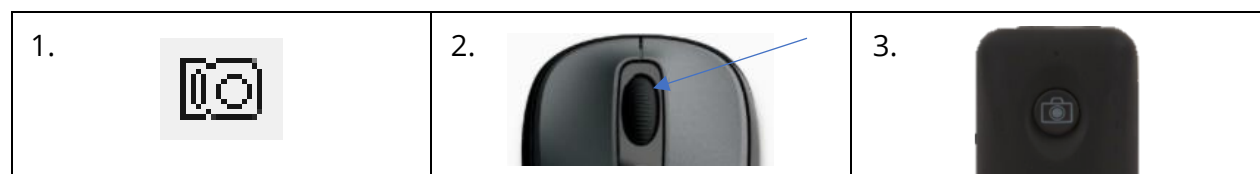
Open the Image View Bar to view captured images



Capturing Images and Video

First and most importantly, you must get the image you wish to capture on the screen. Then, there are three ways you can capture images with the *Firefly Digital Camera*:

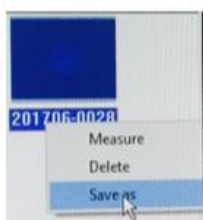
1. Click the Camera icon in the tool bar.
2. Press the scroll wheel (center) button on your mouse.
3. Press the Capture button on the *Firefly Digital Camera*.



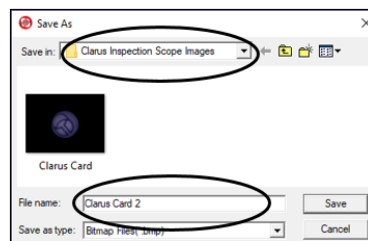
Saving Photos

To save the images you have just captured to a new location, find the image you wish to save, then right click on the photo and click "Save as." Next, select the location from the dropdown menu and select a name for the file (as shown below).

Right Click



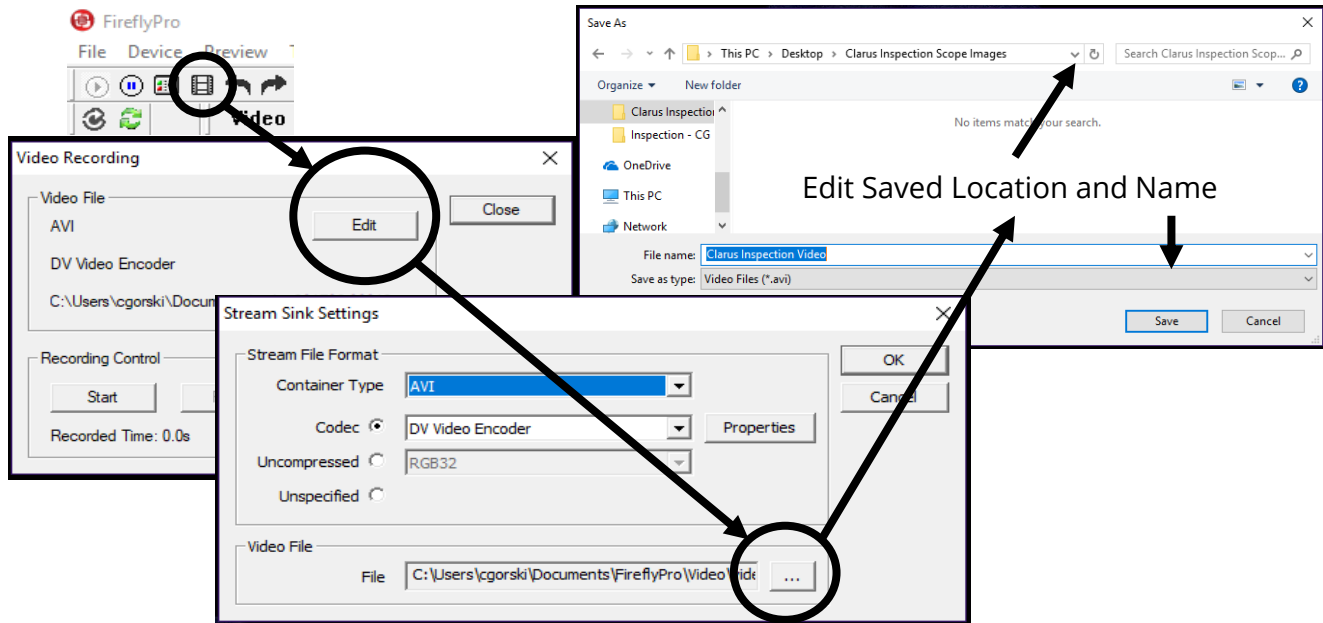
Dropdown To Select Location



Select File Name

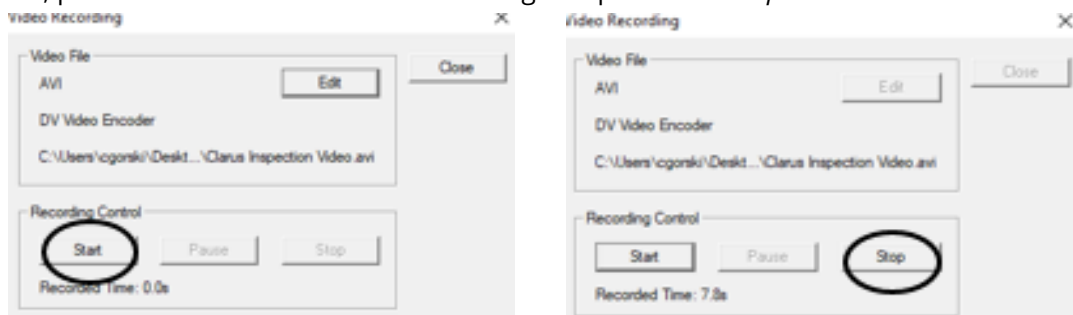
Saving Videos

To start a video capture, start by clicking the film icon in the toolbar. This will create a pop-up window titled "Video Recording." To change the name and save location, click "Edit." Then click on the ellipse button (...) in the bottom right of the pop up window. Finally, change the file name and location to desired name and location.



Capturing Video

To record, press the "Start" icon to start recording and press the "Stop" icon when finished.



Power Off

Slide the power button to the "OFF" position to turn the *Firefly Digital Camera* off. Exit the Firefly software application. You can then unplug the USB cord from the computer.

NOTE: You must re-open the software each time you power off or disconnect the camera.

Firefly Support

Questions about the camera and software may be directed to Firefly. Email your name and phone number (or best way to reach you) to:

Email:

➤ support@fireflyglobal.com

Website:

➤ www.fireflyglobal.com

Using the PureClear™ Inspection Scope

This section covers use of the *PureClear Inspection Scope* including care, handling, examples of what to look for during the inspection process, and cleaning the *PureClear Scope*.

Before Use

- The *PureClear Inspection Scope* is supplied non-sterile (see cleaning instructions on page 17).
- Verify external surfaces of the *PureClear Inspection Scope* are smooth and free of protrusions or sharp edges.
- Verify light output from tip of *PureClear Inspection Scope* (if necessary, see troubleshooting section on page 18).
- Verify image by viewing from the eyepiece or on your monitor (if necessary, see troubleshooting section on page 18).

Use of the *PureClear Inspection Scope*

Grasp the *PureClear Inspection Scope* near its end and gently insert into the intended device (see table on page 3). Use short advancements while keeping your fingers close to the device's opening. View through the eyepiece or monitor while inserting into the device. If an obstruction hinders the path of the *PureClear Inspection Scope*, gently attempt to manipulate or rotate the device to avoid the obstacle.



Handling and Care

Thin optical fibers can be fragile. When handling the *PureClear Inspection Scope*, avoid sharp edges, excess force, and tight corners.



Near Maximum Bend

Areas to Inspect

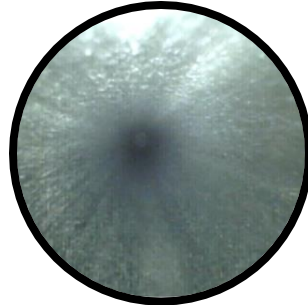
Pay special attention to narrow channels, lumens and internal components not visible to the unaided eye during reprocessing. Refer to the manufacturer's Instructions for Use (IFU) of the device you are inspecting as a guide to critical areas and components to inspect. Visually inspect any area and component where the manufacturer's IFU emphasizes cleaning with a brush.

Examples of What to Look For

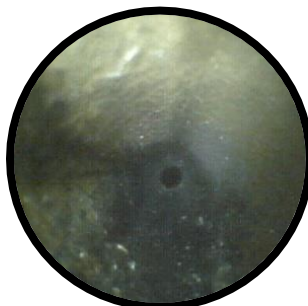
A frequently asked question is, "What do I look for?" In general, the answer is things that don't belong, like debris and damage, just as you would when inspecting the outside of the device. Here are some examples of things to look for when inspecting:

Sterile Processing

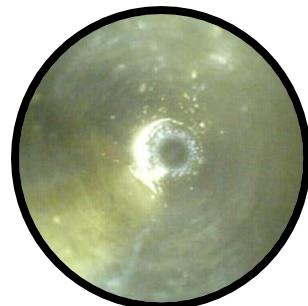
Clean Metal Tubes



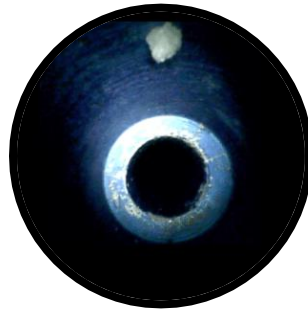
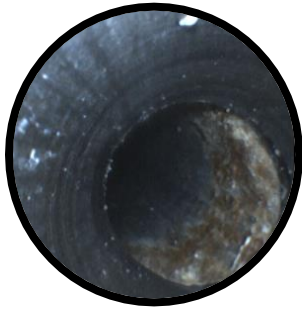
Debris in Metal Tubes



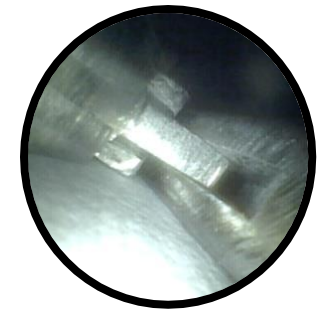
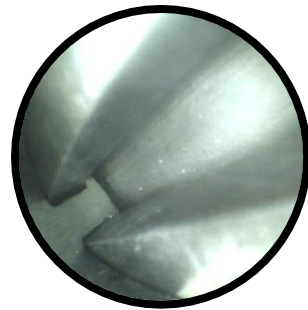
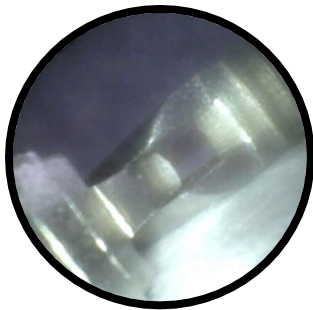
Discoloration in Metal Tubes



Debris in Shaver



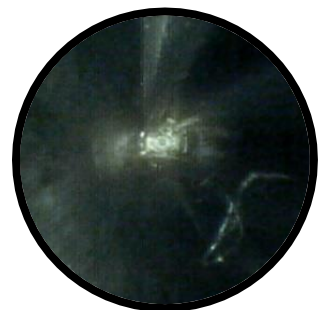
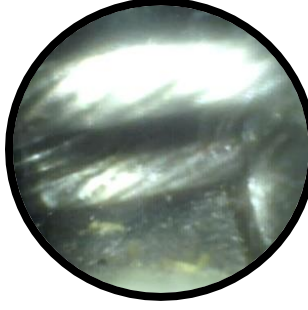
Clean Metal Instruments



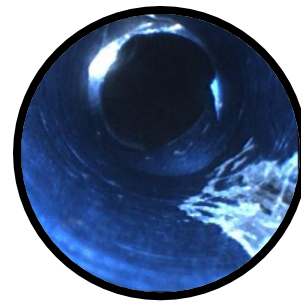
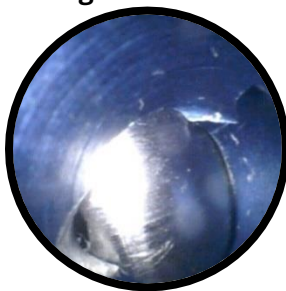
Debris in Metal Instruments



Debris in Robotic Instruments

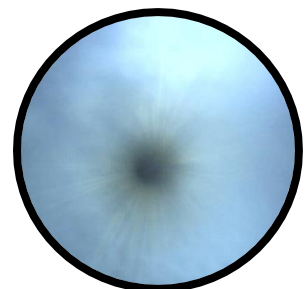
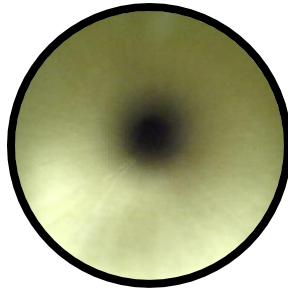
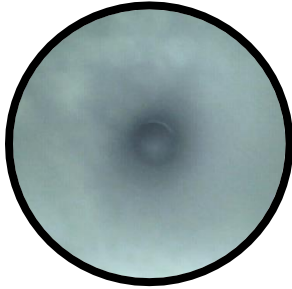


Damage in Shaver

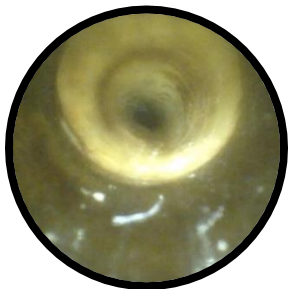


Endoscopy

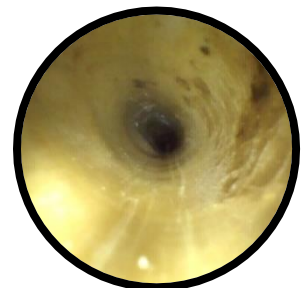
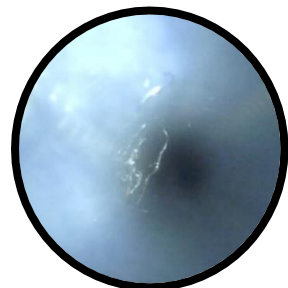
Clean Plastic Channels



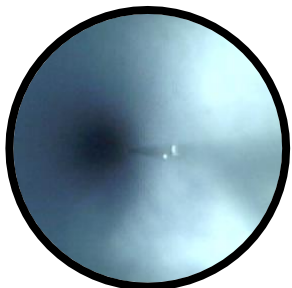
Debris inside Duodenoscope



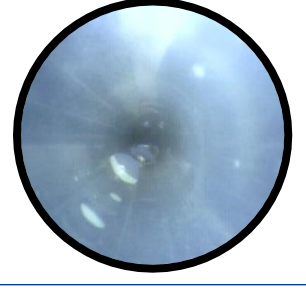
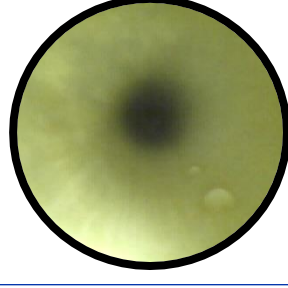
Debris Inside Channel



Damage Inside Channel



Fluid Inside Channel



Cleaning

Before cleaning the *PureClear™ Inspection Scope*, ensure that all components are unplugged or detached. Please refer to the Operator Manual for a complete list of compatible cleaning and sterilization methods.

PureClear™ Inspection Scopes

The inspection scope is designed with no internal channels and smooth surfaces, which make it easy to clean. The inspection scope is compatible with most cold-soak disinfecting or sterilization solutions that are approved for use with flexible endoscopes. Below is a reference chart.

PureClear™ Light Cable

The light cable can be cleaned or sterilized using all the methods described in the chart below for *PureClear Inspection Scopes*. However, unlike *PureClear Inspection Scopes*, the *Light Cable* may be autoclaved. Standard gravity or high speed (flash) methods are compatible with the cables. Do not exceed 270° F (132° C).

PureClear™ LED Light Source

Use cloth dampened with alcohol or commercial cleaners to clean.

Firefly™ Digital Camera

If using the camera system, squeeze the connector tabs to remove the camera from the inspection scope eyepiece. The camera is water-resistant but not water-proof. When cleaning the device, do not submerge the camera body in alcohol, chemicals, or water. The camera lens assembly and camera body may be cleaned with alcohol-based disinfectant wipes, such as ProSpray™ Wipes or similar products.

Cleaning, Disinfecting and Sterilization for <i>PureClear™ Inspection Scopes</i>	Compatible
Enzymatic cleaning solutions	YES
Neutral pH soap and water	YES
Alcohol wipes	YES
Cidex® 2.4% glutaraldehyde solution	YES
Cidex OPA	YES
Tristel™	YES
Chlorine Dioxide	YES
Sporox ® 0.85% Phosphoric Acid Solution	NO
Ethylene Oxide Gas (EtO)	YES
STERIS ® SYSTEM 1E	YES
Sterrad ® 100S, 50, 200, NX, 100NX Systems	YES*
Autoclave, steam or heat	NO

*Tested to 20 cycles

Troubleshooting

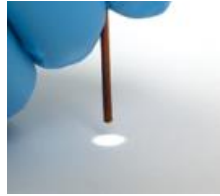
There is very little to no maintenance with the *PureClear™ Inspection Scopes*. However, the thin optical fibers within the scope are fragile and can break when stressed. Broken fibers are often the cause of a full or partial loss of image and unfortunately cannot be repaired.

Condition	Appearance	Cause	Correction
No Light	No image or very dark image looking through scope. No light when scope pointed at surface.	No power to light source	Plug in, power on <i>Light Source</i>
Low Light	No image or very dark image looking through scope. Weak or uneven light pattern when scope pointed at surface.	Dimmer turned down	Turn dimmer knob on the <i>Light Source</i> to increase light output
Low Light	No image or very dark image looking through scope. Weak or uneven light pattern when scope pointed at surface.	Debris on the either distal tip of <i>Light Cable</i>	Wipe ends of light cable. Caution, ensure that the cable has cooled for 5 minutes if in use.
Low Light	No image or very dark image looking through scope. Weak or uneven light pattern when scope pointed at surface.	Broken light fibers in scope	Replace scope. (The user must judge when the <i>Inspection Scope</i> is no longer adequate for use, but as a guide, when 10% of the image or illumination has been degraded or lost it is recommended that a replacement be acquired).
Low Light	No image or very dark image looking through scope. Light cables not passing adequate amount of light when testing distal ends of cable.	Broken light fibers in <i>Light Cable</i>	Replace <i>Light Cable</i>
No image or distorted image	No image or heavily distorted, cracked appearance.	Broken image fibers	Replace <i>PureClear Inspection Scope</i>
Overly bright image	White-out type reflection	<i>Light Source</i> is too bright	Adjust <i>Light Source</i> dimmer knob
Blurry Image	Image not clear and the outer ring of the image on the monitor is also not clear	Camera out of focus	Focus <i>Firefly™ Digital Camera</i>
Blurry or overly bright image	Light will often reflect back appear as white-out through scope	Moisture on lens	Wipe off end of <i>Inspection Scope</i> with soft cloth
Blurry Image or overly bright image	Will often reflect light back and give a bright colored image through scope	Debris or film on lens	Wipe off end of <i>Inspection Scope</i> with soft cloth

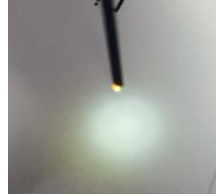
Tips for Troubleshooting

Checking Inspection Scope for Low Light

A bright solid ring should appear when pointing down at a surface at close range.



Normal uniform
circular field of light



Weak indistinct light pattern,
This can indicate a frayed tip,
as shown here

Checking Light Cable for Low Light

Hold one end of the light cable up to ambient light and look down the barrel of the opposite end. A normal light cable would transmit a solid 1 mm circle of light. Also look for signs of debris.



Normal



Broken light fibers
weak light

Checking Image Quality

PureClear™ Inspection Scopes can be checked by simply viewing through the eyepiece and observing for a visual defect. When viewing with the eye the image should be immediately in focus. Make sure enough light is available before verifying an image. Bright room lighting is usually enough light to produce a good image. The grid-like pattern is normal and should not be confused with being out of focus or as the cause of a cloudy image. The *PureClear Inspection Scope* should clearly focus at distances of 5 mm or greater.

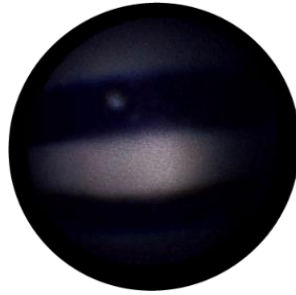


Cleaning of Debris or Moisture

See the cleaning section for specific information; generally, the endoscope lenses and other connections may be wiped down with gauze or other soft cloths with or without alcohol-based cleaning solutions.

Examples of Abnormal Images

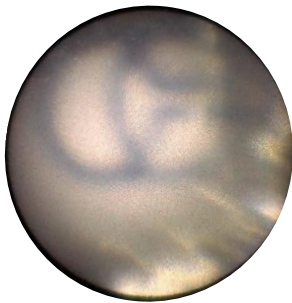
Low Light



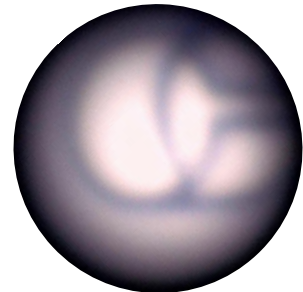
Damaged Light Fiber



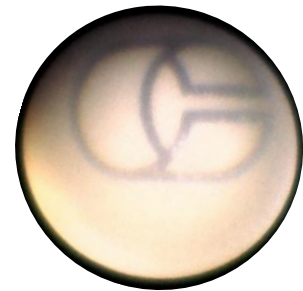
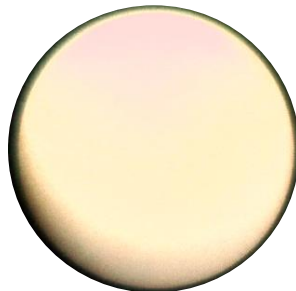
Moisture on Lens



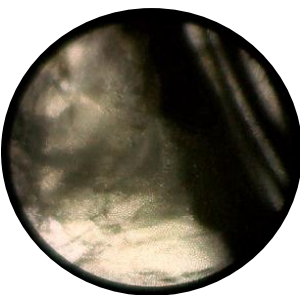
Out of Focus Camera
(Blurry Perimeter)



Debris or Film on Lens



Broken Image Fibers
(Sometimes Appear as No Image or Complete Darkness)



Reference Materials

Inspection Scope Operators Manual 601393-001-A

PureClear™ Light Cable Instructions 601049.001.B

PureClear™ Inspection LED Light Source IFU (106-802-0108)

Firefly GT405 User Manual, Version 1.3

Instructions 635 (Manfrotto Super Clamp)

Instructions 386BC-1 (Manfrotto Nano Clamp)

PureClear™ Inspection Scope Technical Specifications 601406-001-A

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